DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
New Orleans District Office
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

August 16, 2002

VIA FEDERAL EXPRESS—Next Day

FACILITY ID #126920

Robert Klein, Chief Executive Officer
Skyline Medical Center
3441 Dickerson Pike
Nashville, TN 37207

Warning Letter No. 02-NSV-36

Dear Mr. Klein:

Your facility was inspected on July 30, 2002 by a representative of the State of Tennessee acting on behalf of the Food and Drug Administration (FDA). This inspection revealed a serious compromise in the quality of the mammography services offered by your facility.

Under the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 236b, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography.

The recent inspection at your facility revealed the following Level 2 Repeat finding:

Level 2

Failed to produce documents verifying that the interpreting physician [redacted]. met the continuing experience requirement of having interpreted or multi-read 960 mammograms in 24 months (Repeat) – 21 CFR 900.12(a)(1)(ii)(A)

This specific deficiency noted above appeared on your MQSA Post Inspection Report which was given to your facility by the state inspector at the close of your inspection, along with instructions on how to respond to this finding. This finding was also noted for one of your physicians during your May 9, 2001 inspection. Your facility responded to the previous noncompliances in a letter from Melissa Lejsek, RT(R)(M) received in this office June 15, 2001. This response was deemed adequate by our office and acknowledged in a letter dated July 9, 2001.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a violation of the law which may result in FDA taking regulatory action. Regulatory action includes, but is not limited to, placing your facility under a Direct Plan of Correction, charging your facility for the cost of on-site monitoring, seeking civil money penalties up to $10,000 for each failure to substantially comply with MQSA standards, seeking suspension or revocation of your facility's FDA certificate, or seeking a court injunction against further mammography. [See 42 U.S.C. §263b(h)-(j)]

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the cause of this deficiency as identified and to promptly initiate permanent corrective action.

Within 15 working days after receiving this letter, you should notify FDA in writing of each step your facility is taking to prevent the recurrence of any similar violations. Your response should include:

- The specific steps you have taken to correct the Repeat Level 2 violation as outlined in this letter;
- Each step your facility is taking to prevent the recurrence of similar violations;
- Sample records that demonstrate proper record-keeping procedures relating to quality control or any other records that are appropriate to the noncompliance finding (NOTE: Patient names or identification should be deleted from any copies submitted).

If your facility is unable to complete this corrective action within 15 working days, you should state the reason for the delay and the time within which the correction will be completed.

Your reply should be directed to Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217, telephone 615/781-5389, extension 125, with a copy to the State of Tennessee. Should you have questions regarding the technical aspects of this letter or concerning MQSA standards, you may call Karen Smallwood, Radiation Specialist, at 615/781-5380, extension 144.

Sincerely,

Carl E. Draper

Carl E. Draper
Director, New Orleans District

CED:KRS:man

cc: Mary Helen Short, Administrator
Division of Radiological Health
L & C Annex, 401 Church Street
Nashville, TN 37243-1532

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